	Issue	Question	Response
1	Program Structure	Given health centers role as medical homes and the overall aim of population health management to improve the outcomes of patients while improving efficiencies and reducing the total costs, please provide the rationale for excluding health center PMPs from the Pivot Performance Incentive Program.	There will be an opportunity for bonus payments to health center PCPs based on quality, cost effectiveness and Patient Centered Medical Home (PCMH) recognition if they contract with the Network Entity in their region.
2	Program Structure	We currently have some systems in place to identify cost-efficient Medicaid providers (Provider Profiles, reporting available via EHRs, Gold Standard Prescribers, etc.); have we considered utilizing/improving these systems that are already in place to incentivize providers/entities to provide better outcome-based and more cost-efficient care?	The new payment methodology does build on current systems to better recognize and reward outcome-based, cost-efficient care.
3	Program Structure		Several provider-specific (OB/Gyn, Pediatrics, Family Medicine) meetings and presentations have already been conducted. More provider meetings, webinars and other activites are planned in the coming months. The Agency has also established a page on its website where questions and comments may be submitted. A link to subscribe for email updates is also available on this page. All questions and answers received by the Agency will be posted to this page. Additional communmity engagement activities will be announced as the program is developed.

4	Program Structure	Will there be a visit limit? If so, without patient panels, how will a provider know when a patient has used all of their visit? Many providers' billing is often delayed six months or more due to credentialing timeframes.	Today the same concerns about approaching the 14-visit limit for adults exist. Simply having a panel does not prevent recipients from accessing the ER which also counts toward the 14-visit limit for adults. It will be important for physicians to work with the ACHN entities to manage and educate patients regarding the visit limits.
5	Program Structure	Will Pediatric providers be able to dismiss Medicaid patients that choose to go to Urgent Care centers on a regular basis for illness, but use their Pediatric provider for behavior needs and EPSDT's?	The Primary Care Physician will determine dismissal of any recipient.
6	Program Structure	Will Pediatric providers be required to administer EPSDT's or will any "willing Medicaid provider" be able to administer these screenings?	EPSDT screenings may be provided by any EPSDT provider enrolled with Medicaid without regard to their enrollment status with the ACHN entity.
7	Program Structure	Can individual provider practices set up an ACHN Entity?	Any interested organizations must respond to the Response for Proposal (RFP) to be issued in the near future.
8	Program Structure	Will there be more than 1 ACHN in each region.	There will be only one ACHN entity per region.

9	Program Structure	Dr. Moon mentioned three organizations that they were talking with to help in the areas of infant mortality, substance abuse and obesity/obesity	Alabama Child Health Improvement Alliance (ACHIA) has agreed to work with ACHN to develop Quality Improvement Plans related to Obesity and Obesity Prevention. The Alabama Perinatal Quality Collaborative has agreed to work with ACHN to develop QIPs related to Infant Mortality. The Medicaid Agency is in discussions with the Alabama Department of Mental Health about working with ACHN to develop QIPs related to substance abuse. Other groups may want to reach out to these lead organizations regarding how they might contribute.
10	Structure	Do you see providers being able to provide the same continuity of care when patients will be given a broader freedom to walk in Urgent Care centers for their immediate need?	The ACHN is an outcome-focused effort. Consequently, providers will be incentivized for providing a medical home and for the quality of the care they provide. With the support of care coodinators, more patients will be encouraged to obtain care in an appropriate setting. The Agency does not now and currently has no plan to pay stand alone Urgent Care centers.

	Program Structure	seems that the basis of any Primary Care Case Management Program is patient assignment to a PMP/medical home that is responsible for managing	Most other payers in our state do not use assigned panels. The largest commercial payer (BCBS) uses an attribution methodology and some Medicare plans use an attribution methodology. Medicaid's move to an attribution methodology is consistent with the approach of other payers in our state.
	Program	Since patients will no longer be assigned to a Patient 1st PMP and may see any "Medicaid Primary Care Physician" they choose, please define "Medicaid Primary Care Physician."	Primary Care Physician (PCP) – A physician (M.D. – Medical Doctor or D.O. – Doctor of Osteopathic Medicine) that practices in the specialty designation of family medicine, general internal medicine, pediatrics, and general medicine.
	Program Structure	What type of legal entity must be formed to qualify as an ACHN entity?	The entity must be an Alabama nonprofit entity with an office located in the region, and registered as an Alabama domicile with the Secretary of State.
14	Program Structure	What are the requirements for ownership of an ACHN entity? We understand that providers must serve on the board of directors, but do providers also have to be owners of the entity?	There are currently no requirements for ownership.

	Program Structure	Will there be some limitations as to the number of times a maternity patient can change OB providers during the course of a pregnancy? Frequent patient movement especially in urban areas is a concern in such a time limited treatment span such as pregnancy and the potential impact it will have on overall outcome of care and provider ability to meet set care parameters/benchmarks in order to be eligible for the incentive monies.	The maternity patient must be allowed to change a DHCP once without cause within the first 90 Calendar Days of selecting a DHCP and at any time for just cause, which is defined as a valid complaint submitted orally or in writing to the PCCM-E.
16	Program Structure	Does ACHN encourage Patient homes?	The Agency values Patient-Centered Medical Homes which is why PCMH recognition is incentivized in the ACHN program.
17	Program Structure	For an entity to be eligible to respond to the ACHN, must a final determination letter regarding 501(c)(3) status be obtained, or will the Agency accept either the entity's nonprofit status or the entity's submission of the 501(c)(3) application?	The ACHNs will not be required to obtain 501(c)(3) status. The ACHN must be an Alabama nonprofit organization.
18	Program Structure	How can we prevent recipients from Dr shopping? Since they don't need referral.	Currently in Patient 1st, recipients can change PMPs as often as they choose. Reducing referrals or removing panels will not increase the number of times a recipient changes PMPs. Instead, we believe this will result in a more streamlined system for providers and recipients. The advantage of the ACHN system is that a patient who appears to be "doctor shopping" can be identified and referred to the ACHN for care coordination.
	Program Structure	How will this program affect non PCP providers like radiology and pathology?	Radiologists and pathologists do not qualify to participate in the ACHN program, and will continue to receive referrals and payments as they do today.

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20	Program Structure	How would you budget Networks and also incentivizing networks ?	There is no additional funding for the ACHN. The Agency will be combining Patient 1st, Health Homes, Plan First, and the Maternity programs into a single care coordination delivery system with the goal of a more efficient care coordination system while achieving optimal health outcomes. The primary goal is to spend money differently to achieve better results.
21	Program Structure	If you do not participate with ACHN, will you still have a Patient 1st panel or are you doing away with Patient 1st?	Patient 1st will end with the implementation of the ACHNs. Physicians will no longer have panels.
22	Program Structure	Is there a way to reduce the risk of cherry picking patients physicians discharging patients who don't fill their maintenance medications, for instance, if those physicians are not getting their maximum amount of payment and are trying to obtain it?	The Agency recognizes that some patients are more time and resource intensive. The ACHN bonus system will factor that in by risk adjusting for these patients in the cost-effectiveness calculation. At the same time, the ACHN will be incentivized to provide additional care coordination services to encourage recipients to be more compliant.
23	Program Structure	So, under this program, as a PCP, if you see a new Medicaid patient, you will no longer have to get a referral from the PCP the patient is currently assigned to?	This is correct. The patient will no longer need a referral to see a new PCP.
24	Program Structure	We currently have a panel limit and we are not currently taking new medicaid patients, will our Physicians be required to accept new patients?	No. Physicians may continue to limit the number of Medicaid recipients using some of the same office procedures they use to limit other types of payers.
25	Program Structure	When there is no longer a panel, will we still be able to limit the number of new Medicaid recipients attributed to our practice?	Physicians may continue to limit the number of Medicaid recipients using some of the same office procedures they use to limit other types of payers.

	Program	Will the panels be eliminated prior to the implementation of the full	No. The panels will be eliminated when the
26	Structure	program?	ACHNs are implemented.
27	Program Structure	have on overall outcome of care and provider ability to meet set care	The maternity patient must be allowed to change a DHCP once without cause within the first 90 Calendar Days of selecting a DHCP and at any time for just cause, which is defined as a valid complaint submitted orally or in writing to the PCCM-E.
28	Program Structure	When will ACHN entities be required to contract with providers – Prior to golive or during the 1-year "look back" period prior to incentive payout?	contract.
	Duo 242.22	Will the Agency provide the ACHN entity with specific quality data that	Yes, the Agency will provide summary data on a
29	Program Structure	identifies providers who are not meeting quality metrics? If so, how often and in what format will that reporting occur?	monthly basis to the ACHN entities on the performance of quality measures.
30	Program Structure	Will the Agency require ACHNs to use the RMEDE system for documentation of care coordination activities? If so, please provide the latest technical specifications and an updated user manual for RMEDE, so that potential ACHNs can understand its capabilities as they formulate their concept of operations for the proposal.	No. Technical specifications will be detailed in the RFP.

31	Program Structure	Is it possible for the Entity to contract with current ADPH Care Coordinators? Could these Care Coordinators continue to be housed in the ADPH Clinics? With the above scenario, would these Care Coordinators have to be direct employees of the Entity and not ADPH employees?	The PCCM-E may choose to contract with an organization or agency to provide Care Coordination. The PCCM-E will determine where the Care Coordinators will be located. The Care Coordinators would not have to be direct employees of the Entity.
32	Program Structure	Will there be increased Substance Abuse providers for Medicaid recipients in order to participate in S/A quality improvement projects?	It is not the Agency's intention for the entity to hire or increase the number of substance abuse providers for Medicaid recipients. The Agency expects through the QIP implementation, that the entity will address the prevention and outcomes for those with substance abuse disorders through community outreach, provider education, and care coordination of it's recipients. Please see the following link of Substance Abuse providers that are currently certified by DMH. This list is updated monthly by DMH. http://www.mh.alabama.gov/downloads/SA/SA SDProgramDirectory.pdf
33	Program Structure	Are there any granular statistics that show the challenges for the high-risk individuals in the 5% for each region?	AHRQ is a very well established federal research entity and their statistics on the high utilization and high cost recipients has been shown to also be demonstrated in the Alabama Medicaid population. Additional demographic and summary data will be available for responders after the RFP is released.

Program Structure	Please describe the process the Agency will utilize to assist the PCCM-E in verifying appropriate modes of transportation that will be paid by the Agency.	The PCCM-E Care Coordinators will be assisting recipients in navigating the Agency's Non Emergency Transportation (NET) program as well as local resources.
Program Structure	Please confirm that the PCCM-E will not be required to pay for or provide (i.e.: contracts with transportation providers) non-emergency transportation.	This is correct, the PCCM-E will not be required to pay for or provide non-emergency transportation services.
Program Structure	For these bonus payments, where will the evaluated data originate, RMEDE?	These bonus payments will be paid by Medicaid based on meeting criteria. The data used to calculate the measures will originate from submitted claims.
Program Structure	Please define the oversight provided between the PCCM-E and the Agency.	Specific Information will be included in the RFP.
Program Structure	Will the PCCM-E be required to conduct SBIRT training for Providers and certify the Provider's completion of such training?	No, SBIRT training will continue to be done by the Department of Mental Health as it is today.
Program Structure	Please provide the Agency standards for the case to staff ratios expected for ACHN.	Specific Information will be included in the RFP.
Program Structure	Please confirm that this requirement is for recipients in an "active case management" status, and not the total regional population.	This requirement is for recipients currently receiving care coordination services. This does not preclude the PCCM-E from identifying and engaging with other individuals who would benefit from care coordination.
Program Structure	Please confirm that emergency rooms will be required to report discharges to the Agency in real time, and that reporting will be immediately available to the PCCM-E.	The PCCM-Es will need to coordinate with the hospitals in their region to provide services in a timely manner, as the Health Homes do today.
Program Structure	Please confirm that the Agency will maintain responsibility for publishing and issuing a Provider Directory to recipients.	The Agency will maintain a Provider Directory for recipients.

43	Program Structure	Please provide any requirements the Agency has for the referral process the PCCM-E is to create.	Specific Information will be included in the RFP.
	Program Structure	If enrollees are seeing multiple providers, how do PCCM-E's determine the PCP for the purpose of medication reconciliation and discharge follow-up?	The PCCM-E will follow up with the PCP of the recipient's choice.
45	Program Structure	Will the Agency require the use of RMEDE for case management documentation in this regional case management approach? If not, are there any requirements which need to be followed to exchange information between regional case management systems should a recipient move from one region to another?	The ACHNs will fund their case management system from the funds they receive through the provision of services. Unless the ACHN develops its own system, they will need to contract for that capability. The terms of that agreement will be between the case management system provider and the ACHN. Specific information related to patient transfers will be included in the RFP.
46	Program Structure	Please confirm that the Agency will define the business requirements/guidelines for the transfer process instead of each PCCM-E individually working out those details among regions.	Specific Information will be included in the RFP.
47	Program Structure	How will continuity of care be measured if enrollees are allowed to see any Medicaid provider? For example: If a member is seeing multiple providers, who does the PCCM-E coordinate the plan of care with and provide follow up with post discharge or ER visit?	The PCCM-E will follow up with the PCP of the recipient's choice. Medicaid encourages PCCM-Es to work closely with the recipient to seek a single PCP for the purpose of continuity of care.
48	Program Structure	Please confirm that "implementation date" is the expected go-live date of the program, and does not include the implementation and readiness period prior to go-live.	The implementation date is the expected go-live date.
	Program Structure	Please define the process for submitting disenrollment to the Agency for review and approval.	Specific Information will be included in the RFP.

50	Program Structure	How will the grievance data be made available to the PCCM-E? Will the Agency consider monthly reporting, so that the PCCM-E can work with a member to stop any issues/concerns in a timely manner?	Specific Information will be included in the RFP.
51	Program Structure	Please confirm it is the Agency's expectation that each PCCM-E will self-report on their case management activity for which they get paid. If so, how will the Agency ensure that each PCCM-E is defining all elements the same and providing accurate information?	Specific Information will be included in the RFP addressing requirements for these issues.
52	Program Structure	How will the PCCM-E receive data on Non-Authorized Specialist requests?	The Agency will provide quality and utilization summary data to the PCCM-Es on a monthly basis. The Agency will also provide a monthly list of recipients to be screened by the entity. Prior authorization data would be included if determined it would be necessary and used by the PCCM-Es.
53	Program Structure	Will the utilization information and data be similar to the current ESD tables used by the Health Homes (i.e.; The current Touch Report)?	The Agency will provide quality and utilization summary data to the PCCM-Es on a monthly basis. The Agency will also provide a monthly list of recipients to be screened by the entity. Prior authorization data would be included if determined it would be necessary and used by the PCCM-Es.
54	Program Structure	If every PCCM-E is allowed to use its own case management system, what is the system of truth the Agency will use to validate the touches that determine payment?	The Alabama Medicaid Management Information System (MMIS) is the system of truth and the Agency will use this system to validate the touches that determine payment.
55	Program Structure	Please define the requirements to be paid for the following activities within the General Population: "Intensely Managed", "Moderately Managed" and "Monitoring – Medical Review".	Specific Information will be included in the RFP.

56	Program Structure	On what date did the initial 90-day period start? Have there been any additional requests from CMS extending this period?	The initial 90-day period began on August 2, 2018. The current 90-day period has been paused pending CMS's request for additional information.
57	Program Structure	How will PCPs know if recipients have exceeded their 14 visits or not?	PCPs may check the eligibility file for exceeded visits the same way as they do today.
58	Program Structure	Will visit information be available that info on their verification Portal? Will it be real-time?	Visit information is available on the provider's verification portal. This information is not realtime, but is updated as claims are paid.
59	Program Structure	Will Medicaid continue to use the current quality scorecard system available through the Medicaid Provider Portal?	Medicaid is reviewing the current quality scorecard system to determine future changes.
60	Program Structure	How will I know if my attributed patient happened to have gone elsewhere and gotten an EPSDT(say for instance they could not get an appointment with me in a timely manner and needed the Epsdt sooner than I could do)??? Or say even a New Patient that is transferring to our clinic. Will the agency website have last EPSDT date on the website??	A PCP may view the 'date of last screening' on the eligibility file the same way as they do today.
61	Program Structure	Will the Pharmacy and Provider Lock-In process remain the same in the ACHN model? If yes, if a recipient is in lock-in and the assigned Provider refuses to see the recipient, will they be allowed to switch to another Provider	The pharmacy and provider lock in will remain in the ACHN model. The recipient will be assigned to a provider and will not be allowed to change. If the provider refuses to see the patient, the physician, the patient, or the PCCM-E may contact Medicaid to assist in assigning a different lock-in provider.
62	Drogram	We'd like to get a better understanding of the technical capabilities of RMEDE as we're preparing for ACHN. We're finalizing our operational ConOps, and as you know, RMEDE will play a key role.	All requirements for the Health Information

	r rogram	Specifically, I was wondering if all of the care coordination activities	Management Systems (HIMS) will be provided in
	Structure	(maternity, health home, etc.) would live under one interface, or will they	the ACHN RFP.
			the Achiviti .
C 2		be silo'd? We're particularly interested in whether there is a referral	
63 64		process that includes maternity?	
04		Also, would you be able to send us a copy of the Technical Specs?	
			In the 1915(b) Waiver, SBIRT (screening, brief
			intervention and referral to treatment) services
	Program	Are FQHCs allowed to bill FFS for SBIRT?	are (b)(3) services that may be billed by enrolled
	Structure		providers who have been certified by DMH.
			SBIRT-certified physicians employed by FQHCs
65			may bill these services FFS.
		IP Question 2.	
		In general, the current requirement for a referral from the primary care	
		provider in order to see a specialist has many pros. One exception is when a	
		patient has an orthopedic injury already evaluated in a urgent care setting.	
		These patients should be able to see an orthopedic specialist without having	
	Program	to make an extra visit to a primary care provider.	
	Structure	to make an extra visit to a primary care provider	
		Modifier Question	
		For the convenience of the family, chronic conditions are often assessed at	
		the EPSDT visit and in some cases involve complex adjustments to the	Yes, we understand these issues and we are in
		treatment plan. Other payers allow for a modifier to be added to the well	the process of actively looking at the billing
		visit when significant modifications are required. Could reimbursement be	procedures associated with the EPSDT program
66		revised to include this modifier?	to address the issues you have raised.

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		Alabama Arise has a vested interest in the success of Medicaid	representation with the Alabama Coordinated
		transformation. We have been actively involved in the current reform	Health Networks (ACHN). We learned from the
		process from its beginnings in 2012. The 2013 RCO law and 2015 ICN law	RCOs and ICNs and believe that consumers and
	Program	were exemplary in their provisions for consumer oversight via governing	other stakeholders such as FQHCs, Community
	Structure	board representation and advisory committees. Now that those two laws	Mental Health Centers, and Substance Abuse
		are no longer applicable, we are concerned that robust consumer oversight	treatment facilities, are all vital to the program.
		is no longer guaranteed.governance of Alabama Coordinated Health	
67		Networks (ACHNs) falls short of the RCO benchmark.	
		We applaud Alabama Select for maintaining – and even strengthening – the	
		ICN consumer oversight provisions in the new environment. However, the	
		current plan for	
		We have raised this issue numerous times and have yet to see meaningful	
		movement from the state. We continue to believe that the ACHN plan	
		cannot achieve its goals of better care, better outcomes and lower cost	
		without robust consumer involvement in Medicaid policymaking. For more	
		detail, we offer the following observations and recommendations:	
		• The RCO consumer advisory structure, while uneven and often frustrating	
		or absent altogether, offers important lessons for the ACHNs. The best	
		examples (such as a transportation forum prompted by consumer	Therefore, the ACHNs are required to have a
		representatives in the Viva Region B RCO) illustrate that consumer input can	Consumer Advisory Committee (CAC) in which
		help shape Medicaid policy priorities. 1) The RCO consumer advisory	20% of the Committee must be consumers. The
		structure, while uneven and often frustrating or absent altogether, offers	consumer representative may be a recipient,
		important lessons for the ACHNs. The best examples (such as a	parent/caretaker or an advocacy organization
		transportation forum prompted by consumer representatives in the Viva	representative.
		A statutory provision that limited RCO consumer representatives to direct	
		Medicaid beneficiaries was a serious hindrance to effective consumer	
		engagement. The inclusion of parents and caregivers as potential consumer	
		representatives for the ACHNs is a major breakthrough that vastly increases	

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We feel one consumer representative on each ACHN board is inadequate.	
We strongly recommend at least two consumer representatives. Peer	
support is vital for consumer representatives at policy tables dominated by	
health care and business professionals. In response to our previous appeals,	
Medicaid and ACHN officials have responded that adding another consumer	
representative to the board would throw the membership formula out of	
balance, prompting requests for additional members by other stakeholders.	
We urge you to consider that Medicaid beneficiaries are not a stakeholder	
type, comparable to hospitals or community mental health centers, but	
rather a stakeholder class, comparable only to risk-bearing providers and	
non-risk-bearing providers. By this measure, the addition of one consumer	
representative would enhance the stakeholder balance, not upset it.	
Medicaid plans to retain the Citizens' Advisory Committee (CAC) model,	
perhaps under the name Consumer Advisory Council. One of the frustrations	
in the RCO context was a frequent lack of coordination/communication	
between the CACs and the boards. Too often, the CAC member appointed to	
the board was not regarded as a true consumer liaison by the board and the	
RCO. Consumer concerns often didn't receive adequate attention on the	
board agenda. We strongly recommend making consumer engagement (for	
example, as spelled out in the RCO statutory provision for the CACs) an	
explicit responsibility of the boards. A standing high-level agenda item for	The ACHNs have a requirement for the
consumer concerns at every ACHN board meeting would be another good	Governing Boards to receive a verbal report from
measure.	the CAC at each meeting
 Arise is working to identify "community contacts" around each region who 	
can serve as local liaisons for the formal consumer advisors and	
representatives. We think this network will provide a level of support that	
We recommend the use of teleconferencing and other remote meeting	
capacities to accommodate the financial, mobility and other limitations of	The Agency will permit teleconferencing of the
consumer representatives.	ACHN's CAC and Board Meetings

In summary, we urge you to support a strong consumer voice in Medicaid transformation by asking Medicaid to include the following provisions in its waiver request for the ACHN plan: • Each ACHN board will have at least two consumer representatives (the CAC chair and co-chair).	
 waiver request for the ACHN plan: Each ACHN board will have at least two consumer representatives (the CAC chair and co-chair). 	
Each ACHN board will have at least two consumer representatives (the CAC chair and co-chair).	
CAC chair and co-chair).	· · · · · · · · · · · · · · · · · · ·
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Each ACHN board meeting will include an opportunity for a report from	
the CAC.	
We believe effective engagement of consumer representatives is a key to	
the success of the Alabama Coordinated Health Networks. Thank you for	
considering our concerns.	
Program Please confirm the Managed Care division within the Agency, and not the The Managed	d Care Division will be responsible
68 Structure PCCM-E, will complete this activity. for confirming	ng eligibility for PCMH recognition
Program If quality bonus payments are not calculated until May/June for the previous For at least for	our quarters, all practice groups will
69 Structure year, when will Providers receive the payments? automatically	y receive a full quality bonus
PCCM-E will r measures but providers to t assist with th	is payment to the providers, the not be part of the calculation of the it will be expected to work with help improve their performance. To his collaboration, the Agency will thly quality reports on all of its
For the PCCN calculations of performed by send monthly	M-E quality incentive payments, the of the quality measures will be y the Agency but the Agency will y quality reports to assist the PCCM-oring its performance.
	nt of the Agency to renew the waiver
71 Structure the waiver's 2 year demonstration period is over? after the initi	ial two year period.
Program Does this pool include bonus payments to both the PCCM-Es and the The designate	ed \$15.0 million is for bonus
	actively participating primary care

Program Structure	In previous FAQs, the Agency stated that ACHNs must be 501(c)3 non-profits. An entity can be a non-profit without filing for a 501(c)3 designation with the IRS. By requiring an ACHN entity to obtain a 501(c)3 IRS status, the Agency is also requiring an ACHN's Governing Board members and officers to publicly disclose all of their personal income and investments. This is a risk to any entity proposing to become an ACHN and could inhibit the ACHN's ability to secure interested candidates on its Governing Board. Please confirm that the Agency intends for ACHNs to (1) have a non-profit legal status under Alabama law and (2) file as a 501(c)3 entity with the IRS.	The ACHN must be an Alabama nonprofit organization but will not be required to apply for a 501(c)(3) designation with the IRS.
Program Structure	What is the current status of CMS' review and approval of the Plan?	The Agency has submitted the Waiver to CMS and expects an approval before the end of 2018 or early 2019.
Program Structure	Will Readiness Assessment be conducted before CMS' approval of the plan?	The Agnecy has submitted the Waiver to CMS and expects an approval before the end of 2018 or early 2019.
Program Structure	Will the Agency award the RFP without CMS' approval of the Plan?	The Agency has submitted the Waiver to CMS and expects an approval before the end of 2018 or early 2019.

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